

I CLAIM:

1. A method of treating advanced prostate cancer comprising administering to a patient having advanced prostate cancer an androgen suppressing amount of a luteinizing hormone releasing hormone agonist analog and an amount of calcitriol sufficient to enhance the effectiveness of luteinizing hormone releasing hormone agonist analog against the advanced prostate cancer relative to treatment with luteinizing hormone releasing hormone agonist analog alone.

5 2. The method of claim 1 wherein the luteinizing hormone
10 releasing hormone agonist analog is a nonapeptide or decapeptide having the structure: 5-oxo-L-Pro-L-His-L-Trp-L-Ser-L-Tyr-Xaa-L-Leu-L-Arg-Yaa (SEQ ID NO: 1), wherein Xaa is a D-amino acid residue or a modified D-amino acid residue; and Yaa is a modified proline residue or a dipeptide comprising a proline residue and a modified glycine residue.

15 3. The method of claim 2 wherein Xaa is a residue selected from the group consisting of O-t-butyl-D-Ser, D-Leu, D-Trp, 2-methyl-D-Trp, N-benzyl-D-His, and 3-(2-naphthyl)-D-Ala.

20 4. The method of claim 2 wherein Yaa is a residue selected from the group consisting of N-ethyl-L-prolinamide, L-proylcarbazamide, L-prolylglycinamide, and N-ethylprolylglycinamide.

5. The method of claim 1 wherein the calcitriol is in the form of an injectable solution comprising about 1 to about 30 micrograms per milliliter of calcitriol in an isotonic saline medium and a sufficient quantity of nonionic surfactant to solubilize the calcitriol therein.

25 6. The method of claim 5 wherein the nonionic surfactant is a polysorbitan.

7. The method of claim 6 wherein the quantity of the polysorbitan is in the range of about 1 to about 10 milligrams per milliliter.

30 8. The method of claim 5 wherein the injectable solution further comprises about 1 to about 15 milligrams per milliliter of ascorbic acid.

9. The method of claim 5 wherein the injectable solution further comprises about 2 to about 6 milligrams per milliliter of ascorbic acid.

10. The method of claim 5 wherein the injectable solution

further comprises about 1 to about 2 milligrams per milliliter of ethylenediamine tetraacetic acid or a salt thereof.

11. The method of claim 5 wherein the injectable solution further comprises about 5 to about 30 micrograms per milliliter of calcitriol, about 5 1 to about 15 milligrams per milliliter of ascorbic acid, and about 1 to about 2 milligrams per milliliter of ethylenediamine tetraacetic acid or a salt thereof, in an isotonic saline medium; and a sufficient quantity of nonionic surfactant to solubilize the calcitriol therein.

12. The method of claim 11 wherein the nonionic surfactant is a 10 polysorbitan.

13. The method of claim 12 wherein the quantity of the polysorbitan is in the range of about 1 to about 10 milligrams per milliliter.

14. The method of claim 1 wherein the calcitriol is administered weekly at a dosage in the range of about 0.1 to about 20 micrograms per kilogram, 15 based on the weight of the patient in kilograms.

15. The method of claim 1 wherein the calcitriol is administered weekly at a dosage in the range of about 0.5 to about 10 micrograms per kilogram, based on the weight of the patient in kilograms.

16. The method of claim 1 wherein the luteinizing hormone 20 releasing hormone agonist analog comprises leuprolide, goserelin, or a salt thereof.

17. The method of claim 16 wherein the leuprolide is administered subcutaneously as a daily injection of solution of leuprolide acetate in an isotonic saline solution at a dosage of about 1 milligram per day.

25 18. The method of claim 16 wherein the leuprolide, goserelin, or salt thereof is in the form of an injectable, sustained release depot formulation.

19. The method of claim 18 wherein the leuprolide is administered a single intramuscular injection per week of about 7.5 mg of 30 leuprolide in the form of a sustained-release depot formulation.

20. The method of claim 18 wherein the leuprolide is administered a single intramuscular injection per month of about 7.5 mg of leuprolide in the form of a sustained-release depot formulation.

21. The method of claim 18 wherein the leuprolide is administered as a single intramuscular injection every three months of about 11.75 mg of leuprolide in the form of a three-month, sustained-release depot formulation.

5 22. The method of claim 18 wherein the leuprolide is administered as a single intramuscular injection every four months of about 30 mg of leuprolide in the form of a four-month, sustained-release depot formulation.

23. The method of claim 18 wherein the leuprolide is administered subcutaneously in the form of a one-year, sustained release implant containing about 65 mg leuprolide per implant.

10 24. The method of claim 18 wherein the goserelin is administered subcutaneously in the form of a one-month sustained release implant containing about 3.6 mg of goserelin per implant

15 24. The method of claim 18 wherein the goserelin is administered subcutaneously in the form of a three-month sustained release implant containing about 10.8 mg of goserelin per implant.